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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,260	POYNARD, THIERRY	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-36* is/are pending in the application.

4a) Of the above claim(s) *23,26 and 29-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-22,24,25 and 36* is/are rejected.

7)☒ Claim(s) *27 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/687,459.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/6/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of fibrotic disease and liver fibrosis species of disease, the set of six markers of claim 25 as the species of markers, and the function f1 of claim 27 in the reply filed on 30 March 2006 and the telephonic conversation of 30 May 2006 is acknowledged. The traversal is on the ground(s) that a search burden does not exist to examine all species. This is not found persuasive because each species is mutually exclusive and the search for each species is different due to the differences in subject matter.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 23, 26, and 29-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 30 March 2006 and the telephonic conversation of 30 May 2006.

3. After further consideration of claim 28, the species of function of f1-a will be rejoined and examined with the elected function species of f1 of claim 27 due to their common subject matter.

Information Disclosure Statement

4. The Information Disclosure Statement filed 06 October 2003 does not contain a legible copy of each reference listed on the list of references. The references are stated to be present in parent Application No. 09/687459, however the missing reference is not in the application file. This is apparently an error by the Office. Consequently the missing reference has been listed as not considered in the signed copy of the list of references attached to this Office action. If the

applicants provide a legible copy of the missing reference in response to this Office action, the reference will be considered under 37 CFR 1.97(f), and a signed copy of the list of references indicating consideration of the missing reference will be provided to the applicants without the necessity of the applicants filing a second Information Disclosure Statement. The Office regrets any inconvenience this may cause the applicants.

Claim Objections

5. Claims 27 and 28 are objected to because of the following informalities:

Claims 27 and 28 contain multiple periods (one at the end of each function species)

Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title

Claim 36 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to literature consisting of instructions for a method. The MPEP states in 706.03(a):

706.03(a) Rejections under 35 U.S.C. 101

SUBJECT MATTER ELIGIBILITY

Patents are not granted for all new and useful inventions and discoveries. The subject matter of the invention or discovery must come within the boundaries set forth by 35 U.S.C. 101, which permits patents to be granted only for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." The term "process" as defined in 35 U.S.C. 100, means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

See MPEP § 2105 for patentability of microorganisms and MPEP § 2106 - § 2106.02 for patentability of mathematical algorithms or computer programs.

Decisions have determined the limits of the statutory classes. Examples of subject matter not patentable under the statute follow:

Printed Matter

For example, a mere arrangement of printed matter, though seemingly a "manufacture," is rejected as not being within the statutory classes. See In re Miller, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); Ex parte Gwinn, 112 USPQ 439 (Bd. App. 1955); and In re Jones, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is indefinite for recitation of the term "dosage" in line 3. It is not clear if the term means administration of a marker or measurement of an amount of a marker.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 20, 21, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Teare et al. (reference A16 in the information disclosure statement filed 06 October 2003).

The claims are drawn to a method of diagnosing hepatic fibrosis disease comprising identifying at least 4 serological factors that significantly correlate with hepatic fibrosis by a logistic function and analyzing the values of the at least 4 serological factors in the serum or plasma of a patient. In some embodiments the age and gender of the patient is taken into account.

Teare et al. shows a combination of PGA and PIIIP tests that comprise measurements of serological levels of apoA1, gamma-glutamyl transpeptidase (GGT), prothrombin time (PT) and aminoterminal type III procollagen propeptide (PIIIP). The combined tests are shown to correlate with primary biliary cirrhosis in table 2 and on page 897. Patients used for the study to determine correlation with disease were screened for age and sex on page 895.

11. Claims 20, 21, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Naveau et al. (reference A11 in the information disclosure statement filed 06 October 2003).

The claims are drawn to a method of diagnosing hepatic fibrosis disease comprising identifying at least 4 serological factors that significantly correlate with hepatic fibrosis by a logistic function and analyzing the values of the at least 4 serological factors in the serum or plasma of a patient. In some embodiments the age and gender of the patient is taken into account.

Naveau et al. shows a combination of tests that comprise measurements of serological levels of alpha-2-macroglobulin (A_2 m), apoA1, gamma-glutamyl transpeptidase (GGT), and prothrombin time (PT). A linear discriminant function analysis to assess the significance of the test is shown on page 2428. The combined tests are shown to correlate with cirrhosis and hepatic fibrosis in table 5 and alcoholic liver disease in table 6. Patients used for the study to determine correlation with disease were screened for age and sex on page 2427 and table 4.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

14. Claims 20, 21, 22, 24, 25, and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, and 14 of U.S. Patent No. 6,631,330. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2, 3, and 14 of U.S. Patent No. 6,631,330 are species of instant claims 20, 21, 22, 24, 25, and 36.

Allowable Subject Matter

15. Claims 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

John S. Brusca 25 June 2006

John S. Brusca
Primary Examiner
Art Unit 1631

jsb